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MAY 27 2009

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
PiGalileo Screw Targeting System V1.0

Date of Summary: 02/05/2009

Contact Person and Address
Susan Bell
Regulatory Affairs Specialist
Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116
(901) 399-5412

Name of Device: Smith & Nephew PiGalileo Screw Targeting System V1.0
Common Name: Computer Assisted Surgery System

Device Description
The PiGalileo Screw Targeting System is a computer controlled electromagnetic tracking system. It assists the surgeon in locating and positioning screws in an intramedullary nail implant during orthopedic trauma surgery.

The link between the sterile surgical area (patient) and the instrument system is provided through an electromagnetic tracking system. Electromagnetic spatial measurement systems determine the location of instruments that are embedded with sensor coils. When the sensor-embedded instrument is placed inside controlled, varying magnetic fields, voltages are induced in the sensor coils. These induced voltages are used by the measurement system to calculate a 3D virtual position of the instrument. Because the magnetic fields are of a low field strength and can safely pass through human tissue, location measurement of an object is possible without the line-of-sight constraints of an optical spatial measurement system that requires a camera.

Device Classification
21 CFR 882.4560 Stereotaxic Instrument – Class II

Indications for Use
The Smith & Nephew PiGalileo Screw Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew PiGalileo Screw Targeting System V 1.0 is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Substantial Equivalence Information
The overall design and indications for use/intended use of the PiGalileo Screw Targeting System is substantially equivalent to previously cleared devices listed below.

Predicate Platform System

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
Smith & Nephew, Inc	PiGalileo Navigation System (4th Generation)	K080875	7/18/2008

Predicate Electromagnetic Tracking Technology Systems

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
Medtronic Navigation, Inc	SNT StealthStation AxiEM Imageless Knee Module	K043088	01/05/2005

Indications for Use

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
BrainLAB AG	Vector Vision Trauma	K012448	03/14/2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Smith & Nephew, Inc.
% Ms. Susan Bell
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K090420
Trade/Device Name: PiGalileo Screw Targeting Software Application V1.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: May 13, 2009
Received: May 14, 2009

Dear Ms. Bell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: PiGalileo Screw Targeting Software Application V1.0

Indications for Use:
The Smith & Nephew PiGalileo Screw Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew PiGalileo Screw Targeting System V 1.0 is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090420